via CDX

Document Processing Desk (DCI/AD)
Attn: Reevaluation Team Leader, PM 36
US EPA (7501P)
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202

Lonza Inc.
412 Mount Kemble Avenue, Suite 200S
Morristown, NJ 07960

Jennifer DePietro
Regulatory Affairs Associate
Regulatory Assurance

Tel 201-316-9293
jennifer.depietro@lonza.com

March 5, 2019

SUBJECT: ID # GDCI-067300-1493 - 1,3-Propanediamine, N-(3-aminopropyl)-N-dodecyl-
Lonza Inc. EPA Company 6836

THIS SUBMISSION IS NOT SUBJECT TO FEES UNGER PRIA

Dear Sir or Madame:

Lonza Inc. is responding to the subject Data Call-In. We are voluntarily cancelling EPA product registration 6836-284, which is listed on the Data Call-In Response Form.

For the remaining registrations, Lonza has selected the “I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response" option in CDX.

If you have any questions or need any additional information, please feel free to contact me at 201-316-9293 or via email at jennifer.depietro@lonza.com.

Sincerely,
Lonza Inc.

Jennifer DePietro
Regulatory Affairs Associate

90-DAY RESPONSE (this is a re-submission)				
DCI Number: GDCI-067300-1493				
Data Call-In Information				
Company Name	**LONZA INC.**			
Company Address	**90 BOROLINE ROAD ALLENDALE, NJ 07401**			
DCI Type	**Generic**			
Issued Date	**12/11/2018**			
90-Day Response Deadline	**03/21/2019**			
CRM Information	**opp_ad_reevaluation_DCI_team@epa.gov**			
Chemical Name	**1,3-Propanediamine, N-(3-aminopropyl)-N-dodecyl-**			
Chemical Number	**067300**			
90-Day Response Information				
Resubmission	**Yes**			
Tracking Number	**CDX_DCI_2019_000162**			
EPA Product Registration Number(s)				
6836-329	**I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."**			
6836-284	**I wish to cancel this product registration voluntarily.**			
EPA Product Registration Documents: 6836-284				
File Name	**File Type**	**MRID**	**CBI**	**Submitted Date**
6836-284 Cancellation_2019 GDCI Response.pdf	**Company Letter**	**N.A.**	**N**	**03/05/2019**
6836-283	**I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."**			
Guideline Requirement Number(s)				
Guideline Requirement Number - 835.1110				
Study Title	**Activated sludge sorption isotherm**			
Protocol	**N**			
Target Submission Date	**12/11/2019**			
Use Pattern	**R; S; T; U; V; X**			
Test Substance	**TGAI**			
Time Frame	**12 month(s)**			
Footnote(s)	**15. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0003.**			
Registrant Response	**Developing Data**			
Guideline Requirement Number - 835.1230				
Study Title	**Sediment and soil absorption/desorption for parent and degradates**			
Protocol	**N**			
Target Submission Date	**12/11/2019**			
Use Pattern	**R; S; T; U; V; X**			
Test Substance	**TGAI or PAIRA**			
Time Frame	**12 month(s)**			

Footnote(s)	
Registrant Response	**Submitting Existing Data**
Guideline Requirement Number - 835.3110	
Study Title	**Ready biodegradability**
Protocol	**N**
Target Submission Date	**12/11/2019**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI**
Time Frame	**12 month(s)**
Footnote(s)	**3. The results of the Activated Sludge Respiration Inhibition Test (ASRI) will determine which of the four biodegradation tests are required. If the ASRI test EC50 is less than or equal to 20 mg/L, then either the (i) Biodegradation in Activated Sludge Study, GLN 835.3280 or (ii) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, GLN 835.3240, or (iii) the Porous Pot Test, GLN 835.3220 are required. If the ASRI test EC50 is greater than 20 mg/L, then the registrant is required to conduct either: (i) Ready Biodegradability or (ii) a) Biodegradation in Activated Sludge or b) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units or c) the Porous Pot Test. If the Ready Biodegradability study is conducted and passes, then no further testing is required. If, however, the antimicrobial fails the Ready Biodegradability study, then either the a) Biodegradation in Activated Sludge or b) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, or c) the Porous Pot study is required. 4. The need for these biodegradation studies is based on results of an Activated Sludge Respiration Inhibition test. 14. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0017. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.**
Registrant Response	**Submitting Existing Data**
Guideline Requirement Number - 835.3220	
Study Title	**Porous pot test**
Protocol	**N**
Target Submission Date	**12/11/2019**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI**
Time Frame	**12 month(s)**
Footnote(s)	**3. The results of the Activated Sludge Respiration Inhibition Test (ASRI) will determine which of the four biodegradation tests are required. If the ASRI test EC50 is less than or equal to 20 mg/L, then either the (i) Biodegradation in Activated Sludge Study, GLN 835.3280 or (ii) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, GLN 835.3240, or (iii) the Porous Pot Test, GLN 835.3220 are required. If the ASRI test EC50 is greater than 20 mg/L, then the registrant is required to conduct either: (i) Ready Biodegradability or (ii) a) Biodegradation in Activated Sludge or b) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units or c) the Porous Pot Test. If the Ready Biodegradability study is conducted and passes, then no further testing is required. If, however, the antimicrobial fails the Ready Biodegradability study, then either the a) Biodegradation in Activated Sludge or b) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, or c) the Porous Pot study is required. 4. The need for these biodegradation studies is based on results of an Activated Sludge Respiration Inhibition test. 13. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0024. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.**
Registrant Response	**Submitting Existing Data**
Guideline Requirement Number - 835.3240	
Study Title	**Simulation Test-Aerobic Sewage Treatment-Activated Sludge**
Protocol	**N**
Target Submission Date	**12/11/2019**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI**
Time Frame	**12 month(s)**

Footnote(s)	**3. The results of the Activated Sludge Respiration Inhibition Test (ASRI) will determine which of the four biodegradation tests are required. If the ASRI test EC50 is less than or equal to 20 mg/L, then either the (i) Biodegradation in Activated Sludge Study, GLN 835.3280 or (ii) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, GLN 835.3240, or (iii) the Porous Pot Test, GLN 835.3220 are required. If the ASRI test EC50 is greater than 20 mg/L, then the registrant is required to conduct either: (i) Ready Biodegradability or (ii) a) Biodegradation in Activated Sludge or b) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units or c) the Porous Pot Test. If the Ready Biodegradability study is conducted and passes, then no further testing is required. If, however, the antimicrobial fails the Ready Biodegradability study, then either the a) Biodegradation in Activated Sludge or b) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, or c) the Porous Pot study is required. 4. The need for these biodegradation studies is based on results of an Activated Sludge Respiration Inhibition test. 12. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0034. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.**
Registrant Response	**Submitting Existing Data**
Guideline Requirement Number - 835.3280	
Study Title	**Simulation Tests to Assess the Biodegradability of Chemicals**
Protocol	**N**
Target Submission Date	**12/11/2019**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI**
Time Frame	**12 month(s)**
Footnote(s)	**3. The results of the Activated Sludge Respiration Inhibition Test (ASRI) will determine which of the four biodegradation tests are required. If the ASRI test EC50 is less than or equal to 20 mg/L, then either the (i) Biodegradation in Activated Sludge Study, GLN 835.3280 or (ii) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, GLN 835.3240, or (iii) the Porous Pot Test, GLN 835.3220 are required. If the ASRI test EC50 is greater than 20 mg/L, then the registrant is required to conduct either: (i) Ready Biodegradability or (ii) a) Biodegradation in Activated Sludge or b) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units or c) the Porous Pot Test. If the Ready Biodegradability study is conducted and passes, then no further testing is required. If, however, the antimicrobial fails the Ready Biodegradability study, then either the a) Biodegradation in Activated Sludge or b) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, or c) the Porous Pot study is required. 4. The need for these biodegradation studies is based on results of an Activated Sludge Respiration Inhibition test. 11. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0036. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.**
Registrant Response	**Submitting Existing Data**
Guideline Requirement Number - 835.4100	
Study Title	**Aerobic soil metabolism**
Protocol	**N**
Target Submission Date	**12/11/2020**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI or PAIRA**
Time Frame	**24 month(s)**
Footnote(s)	
Registrant Response	**Developing Data**
Guideline Requirement Number - 835.4300	
Study Title	**Aerobic aquatic metabolism**
Protocol	**N**
Target Submission Date	**12/11/2020**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI or PAIRA**
Time Frame	**24 month(s)**
Footnote(s)	

Registrant Response	**Developing Data**
Guideline Requirement Number - 835.4400	
Study Title	**Anaerobic aquatic metabolism**
Protocol	**N**
Target Submission Date	**12/11/2020**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI or PAIRA**
Time Frame	**24 month(s)**
Footnote(s)	
Registrant Response	**Developing Data**
Guideline Requirement Number - 850.1025	
Study Title	**Oyster acute toxicity test (shell deposition)**
Protocol	**N**
Target Submission Date	**12/11/2019**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI, TEP**
Time Frame	**12 month(s)**
Footnote(s)	**6. Only one of either guideline 850.1025 or 850.1055 is required.**
Registrant Response	**Developing Data**
Guideline Requirement Number - 850.1035	
Study Title	**Mysid acute toxicity test**
Protocol	**N**
Target Submission Date	**12/11/2019**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI**
Time Frame	**12 month(s)**
Footnote(s)	
Registrant Response	**Developing Data**
Guideline Requirement Number - 850.1055	
Study Title	**Bivalve acute toxicity test (embryo larval)**
Protocol	**N**
Target Submission Date	**12/11/2019**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI, TEP**
Time Frame	**12 month(s)**
Footnote(s)	**6. Only one of either guideline 850.1025 or 850.1055 is required.**
Registrant Response	**Waiver Request**

Uploaded Documents				
File Name	**File Type**	**MRID**	**CBI**	**Submitted Date**
GDCI-067300-1493 Waiver Request_MRID 50803401.pdf	**Waiver Request**	**N.A.**	**Y**	**03/05/2019**

Guideline Requirement Number - 850.1075	
Study Title	**Fish acute toxicity test, freshwater and marine**
Protocol	**N**
Target Submission Date	**06/11/2020**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI, EP**
Time Frame	**18 month(s)**
Footnote(s)	**5. Results from a study using one estuarine/marine fish species must be submitted to satisfy this requirement.**
Registrant Response	**Developing Data**
Guideline Requirement Number - 850.1300	
Study Title	**Daphnid chronic toxicity test**
Protocol	**N**
Target Submission Date	**12/11/2019**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI**
Time Frame	**12 month(s)**
Footnote(s)	
Registrant Response	**Submitting Existing Data**
Guideline Requirement Number - 850.1400	
Study Title	**Fish early-life stage toxicity test**
Protocol	**N**
Target Submission Date	**12/11/2019**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI**
Time Frame	**12 month(s)**
Footnote(s)	**9. Either freshwater or estuarine/marine, depending on which was most acutely sensitive.**
Registrant Response	**Developing Data**
Guideline Requirement Number - 850.3300	
Study Title	**Modified Activated Sludge, Respiration Inhibition Test**
Protocol	**N**
Target Submission Date	**12/11/2019**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI, EP, PAI**
Time Frame	**12 month(s)**

Footnote(s)	**3. The results of the Activated Sludge Respiration Inhibition Test (ASRI) will determine which of the four biodegradation tests are required. If the ASRI test EC50 is less than or equal to 20 mg/L, then either the (i) Biodegradation in Activated Sludge Study, GLN 835.3280 or (ii) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, GLN 835.3240, or (iii) the Porous Pot Test, GLN 835.3220 are required. If the ASRI test EC50 is greater than 20 mg/L, then the registrant is required to conduct either: (i) Ready Biodegradability or (ii) a) Biodegradation in Activated Sludge or b) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units or c) the Porous Pot Test. If the Ready Biodegradability study is conducted and passes, then no further testing is required. If, however, the antimicrobial fails the Ready Biodegradability study, then either the a) Biodegradation in Activated Sludge or b) Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units, or c) the Porous Pot study is required. 7. OECD Test Guideline 209 can also be used as guidance for this study, available online at http://www.oecd-ilibrary.org/content/book/9789264070080-en. 10. EPA published draft guidance under guideline 850.6800 and has since published final guidance for this study under guideline 850.3300: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0021.**
Registrant Response	**Submitting Existing Data**
Guideline Requirement Number - 850.4400	
Study Title	**Aquatic Plant Toxicity Using Lemna spp**
Protocol	**N**
Target Submission Date	**12/11/2019**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI, TEP**
Time Frame	**12 month(s)**
Footnote(s)	**18. Data for freshwater and marine diatoms and cyanobacteria is needed only if the EC50 for the green algae is less than 1 ppm.**
Registrant Response	**Developing Data**
Guideline Requirement Number - 850.4500	
Study Title	**Algal Toxicity**
Protocol	**N**
Target Submission Date	**12/11/2019**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI**
Time Frame	**12 month(s)**
Footnote(s)	**8. In a Federal Register Notice dated June 27, 2012, EPA split the Public Draft OPPTS 850.5400 test guideline into two test guidelines: OCSPP 850.4500 and OCSPP 850.4550. See Final Test Guidelines; OCSPP 850 Series; Notice of Availability 77 FR 38282, June 27, 2012. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028. 18. Data for freshwater and marine diatoms and cyanobacteria is needed only if the EC50 for the green algae is less than 1 ppm.**
Registrant Response	**Developing Data**
Guideline Requirement Number - 850.4550	
Study Title	**Cyanobacteria (Anabaena flos-aquae) Toxicity**
Protocol	**N**
Target Submission Date	**12/11/2019**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI**
Time Frame	**12 month(s)**
Footnote(s)	**8. In a Federal Register Notice dated June 27, 2012, EPA split the Public Draft OPPTS 850.5400 test guideline into two test guidelines: OCSPP 850.4500 and OCSPP 850.4550. See Final Test Guidelines; OCSPP 850 Series; Notice of Availability 77 FR 38282, June 27, 2012. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028. 18. Data for freshwater and marine diatoms and cyanobacteria is needed only if the EC50 for the green algae is less than 1 ppm.**
Registrant Response	**Developing Data**

Guideline Requirement Number - 870.3465	
Study Title	**90-day inhalation toxicity**
Protocol	**N**
Target Submission Date	**12/11/2020**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI**
Time Frame	**24 month(s)**
Footnote(s)	**1. The use site triggering this data requirement is hard surface disinfectant and sanitizer.**
Registrant Response	**Developing Data**
Guideline Requirement Number - 870.3700	
Study Title	**Prenatal developmental toxicity study**
Protocol	**N**
Target Submission Date	**12/11/2020**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TGAI**
Time Frame	**24 month(s)**
Footnote(s)	**17. Data is needed on a non-rodent species (rabbit preferred).**
Registrant Response	**Submitting Existing Data**
Guideline Requirement Number - 875.1200	
Study Title	**Dermal exposure--Indoor**
Protocol	**Y**
Target Submission Date	**12/11/2020**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TEP**
Time Frame	**24 month(s)**
Footnote(s)	**16. Dermal and inhalation exposure data are needed for the mopping, mechanical sprayer, and foaming generator scenarios.** **20. A protocol must be approved by the Agency prior to the initiation of the study.**
Registrant Response	**Citing a Study**
MRID Number(s)	**48210201, 48231201, 48231901, 48724801, 48375601, 48659001, 48917401, 49434501**
Guideline Requirement Number - 875.1400	
Study Title	**Inhalation exposure--indoor**
Protocol	**Y**
Target Submission Date	**12/11/2020**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TEP**
Time Frame	**24 month(s)**
Footnote(s)	**16. Dermal and inhalation exposure data are needed for the mopping, mechanical sprayer, and foaming generator scenarios.** **20. A protocol must be approved by the Agency prior to the initiation of the study.**
Registrant Response	**Citing a Study**
MRID Number(s)	**48210201, 48231201, 48231901, 48724801, 48375601, 48659001, 48917401, 49434501**

Guideline Requirement Number - 875.1700	
Study Title	**Product Use Information**
Protocol	**N**
Target Submission Date	**12/11/2019**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TEP**
Time Frame	**12 month(s)**
Footnote(s)	
Registrant Response	**Developing Data**
Guideline Requirement Number - 875.2300	
Study Title	**Indoor surface residue dissipation**
Protocol	**N**
Target Submission Date	**12/11/2020**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TEP**
Time Frame	**24 month(s)**
Footnote(s)	**2. The use site triggering this data requirement is disinfectant use on floors. 19. A waiver may be requested for all applications if a residue screening level default at 100% of the application rate does not trigger risk concerns. 20. A protocol must be approved by the Agency prior to the initiation of the study.**
Registrant Response	**Developing Data**
Guideline Requirement Number - 875.2700	
Study Title	**Product Use Information**
Protocol	**N**
Target Submission Date	**12/11/2019**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TEP**
Time Frame	**12 month(s)**
Footnote(s)	
Registrant Response	**Developing Data**
Guideline Requirement Number - 875.2800	
Study Title	**Description of human activity**
Protocol	**N**
Target Submission Date	**12/11/2020**
Use Pattern	**R; S; T; U; V; X**
Test Substance	**TEP**
Time Frame	**24 month(s)**
Footnote(s)	**2. The use site triggering this data requirement is disinfectant use on floors.**
Registrant Response	**Developing Data**
Submitter Information	
Submitter	**Jonathan Walsh**
Submitted Date	**03/07/2019**

Additional Contact(s)	**jennifer.depietro@lonza.com**

I certify, under penalty of law that the information provided in this document is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowing violations.